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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/621,897 07/20/00 SCOTT

R CEPH-1066

EXAMINER

HM12/0924

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ART UNIT	PAPER NUMBER

1633

DATE MAILED:

09/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/621,897	SCOTT ET AL.	
	Examiner	Art Unit	
	Dave Nguyen	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to a gene-targeted, non-human mammal heterozygous for a human Familial Alzheimer's Disease (FAD) mutation comprising a human mutation of the preselin-1 (PS-1 gene), a human FAD Swedish mutation, and a humanized A β gene, offspring thereof, screening and identifying methods, classified in Class 811, subclasses 13 and 14.

II. Claim 27 and 35, drawn to a method of employing the compound identified by the method of claim 19 to treat AD, and the compound itself, readable on Class 514, subclass 44, and Class 536, 23.1.

III. Claims 28 and 36, drawn to a method of employing the compound identified by the method of claim 20 to treat AD, and the compound itself, readable on Class 514, subclass 44, and Class 536, 23.1.

IV. Claims 29 and 37, drawn to a method of employing the compound identified by the method of claim 21 to treat AD, and the compound itself, readable on Class 514, subclass 44, and Class 536, 23.1.

V. Claims 30 and 38, drawn to a method of employing the compound identified by the method of claim 22 to treat AD, and the compound itself, readable on Class 514, subclass 44, and Class 536, 23.1.

VI. Claim 31, drawn to a compound identified by the method of claim 11, readable on Class 536, subclass 23.1.

VII. Claim 32, drawn to a compound identified by the method of claim 12, readable on Class 536, subclass 24.1.

VIII. Claim 33, drawn to a compound identified by the method of claim 11, readable on Class 530, subclass 24.5.

IX. Claim 34, drawn to a compound identified by the method of claim 11, readable on Class 424,

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subclass 184.1.

X. Claims 39-64, drawn to a gene-targeted, non-human mammal heterozygous for a human Familial Alzheimer's Disease (FAD) mutation comprising a human mutation of the preselilin-1 (PS-1 gene) and a human FAD Swedish mutation for Swedish APP695, offspring thereof, screening and identifying methods, classified in Class 811, subclasses 13 and 14.

XI. Claims 65 and 73, drawn to a method of employing the compound identified by the method of claim 57 to treat AD, and the compound itself, readable on Class 514, subclass 44.

XII. Claims 66 and 74, drawn to a method of employing the compound identified by the method of claim 58 to treat AD, and the compound itself, readable on Class 424, subclass 93.21.

XIII. Claims 67 and 75, drawn to a method of employing the compound identified by the method of claim 59 to treat AD, and the compound itself, readable on Class 514, subclass 2.

XIV. Claims 68 and 76, drawn to a method of employing the compound identified by the method of claim 60 to treat AD, and the compound itself, readable on Class 424, subclass 178.1

XV. Claim 69, drawn to a compound identified by the method of claim 49, readable on Class 536, subclass 23.1.

XVI. Claim 70, drawn to a compound identified by the method of claim 50, readable on Class 536, subclass 24.5.

XVII. Claim 71, drawn to a compound identified by the method of claim 51, readable on Class 424,

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indicated is proper, particularly since it would be unduly burdensome for the examiner to search and/or consider patentability of all of the claims as presently pending.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Should a Group of Groups I-XVIII be elected, claims 1-76 are generic to a plurality of disclosed patentably distinct species comprising:

1/ A specific species of human mutation of the preselin-1 (PS-1 gene); Currently, claims 1 and 2 of Group I are generic; and claims 39 and 40 of Group X are generic, for example.

2/ A specific species of a human FAD Swedish mutation; Currently, claims 1 and 2 of Group I are generic; and claims 39 and 40 of Group X are generic, for example.

3/ A specific species of mammal which includes mouse, rodent, pig, monkey, etc.; Currently, claims 1 and 2 of Group I are generic; and claims 39 and 40 of Group X are generic, for example.

4/ A specific named species of tissue sample for use in screening assay should a specific Group claims readable on the screening assay be elected, wherein the tissue sample includes brain tissue, non-brain tissue and body fluids. Currently, claims 11-15, 19-22, and 58-61 are generic, for example.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as indicated in **1/, 2/, 3/, 4/ and 5/ should a group of Groups I-XVIII, which encompasses the listed species be elected, even though this requirement is traversed.**

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is **(703) 305-3015**.

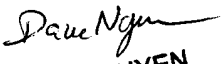
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER



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